

**IN THE UNITED STATES DESIGNATED/ELECTED OFFICE**

International Application No. : PCT/EP2004/002407  
International Filing Date : March 9, 2004  
Priority Date(s) Claimed : April 3, 2003  
Applicant(s) (DO/EO/US) : Werner MEDERSKI et al.

Title: 1-N-(PHENYL)-2-N-(PHENYL)PIRAZOLIDINE-1,2-DICARBOXAMIDE  
DERIVATIVES AS COAGULATION FACTOR XA INHIBITORS FOR THE  
TREATMENT OF THROMBOSES

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

**Timing and Fees**

- ☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
  - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
  - ☒ before the mailing of a first substantive office action (including after filing of an RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- a final rejection under 37 C.F.R. 1.113;
  - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
- ☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:
  - ☐ a final action under 37 C.F.R. § 1.113;
  - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2);
  - ☐ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☒ Copies of materials listed but not attached were cited in an international search report dated August 8, 2004.
- ☐ Not required by 37 CFR § 1.98.
- ☐ Copies of the materials listed are attached (except for the foregoing).

### Non-English Language References

☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

☒ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone

Y = document of particular relevance when it is combined with another such document

A = document defining the general state of the art

O = non-written disclosure

P = intercalated document

T = document cited to understand the theory or principle underlying the invention

E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date

D = cited in the application

L = cited for another reason

& = publication of member of same patent family

☒ Translation of other relevant information on foreign search report

In the search report, "Seite" means page, "Seiten" means pages, "Verbindungen der Formel" means Figure of formula, "Beispiele" means examples, and "das ganze Dokument" means the entire document, "Spalte" means column, "Zeile" means line, "Abbildungen" means claims, "Anspruch" means example, "Zusammenfassung" means summary, and "Tabelle" means table, and "Tabellen" means tables "in der Anmeldung erwaehnt" means cited in the application, "Schema" means scheme, "und" means and, "Absatz" means break, "Abbildung" means figure.

### Other Information

#### Payment of Fees Due (If Any):

☐ A check for \$\_\_\_\_\_ covering the fee identified above is attached.

☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: MERCK-3069

Date: October 3, 2005

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Sheet 1 of 2

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|                        |                        |
|------------------------|------------------------|
| Application Number     | PCT/EP2004/002407      |
| Filing Date            | October 3, 2005        |
| First Named Inventor   | Werner MEDERSKI et al. |
| Group Art Unit         | Unassigned             |
| Examiner Name          | Unassigned             |
| Attorney Docket Number | MERCK-3069             |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials * | Cite No. <sup>1</sup> | U.S. Patent Document |                                      | Name of Patentee or Applicant<br>of Cited Document | Date of Publication of Cited Document<br>MM-DD-YYYY |
|------------------------|-----------------------|----------------------|--------------------------------------|--|---|
|                        |                       | Number               | Kind Code <sup>2</sup><br>(if known) |  |   |
|                        | 1                     | 2002002183           |                                      |  | January 3, 2002                                     |
|                        | 2                     | 2004097550           |                                      |  | May 20, 2004  |
|                        | 3                     | 2003105084           |                                      |  | June 5, 2003  |
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**FOREIGN PATENT DOCUMENTS**

| Examiner<br>Initials * | Cite No. <sup>1</sup> | Foreign Patent Document |                     |                                      | Name of Patentee or Applicant of<br>Cited Document | Date of Publication of Cited<br>Document MM-DD-YYYY | Pages, Columns,<br>Lines, Where<br>Relevant<br>Passages or<br>Relevant Figures<br>Appear | T <sup>6</sup> |
|------------------------|-----------------------|-------------------------|---------------------|--------------------------------------|--|---|--|----------------|
|                        |                       | Office <sup>3</sup>     | Number <sup>4</sup> | Kind Code <sup>5</sup><br>(if known) |  |   |  |                |
|                        | 4                     | WO                      | 0164642             |                                      | Cor Therapeutics Inc                               | September 7, 2001                                   |  | 1              |
|                        | 5                     | WO                      | 02074735            |                                      | Merck Patent GmbH                                  | September 26, 2002                                  |  | 2              |
|                        | 6                     | WO                      | 03024971            |                                      | Procter & Gamble                                   | March 27, 2003                                      |  | 3              |
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| Group Art Unit         | Unassigned             |
| Examiner Name          | Unassigned             |
| Attorney Docket Number | MERCK-3069             |

**NON PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials * | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.   | T <sup>2</sup> |
|------------------------|-----------------------|---|----------------|
|                        | 7                     | Database Medline 'Online! US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; 1972 ROUBAL Z ET AL: "NEWLY SYNTHESIZED PYRAZOLIDINE DERIVATIVES AS POTENTIAL ACTIVATORS OF FIBRINOLYSIS AND ANTIAGGREGATING AGENTS." DATABASE ACCESSION NO. NLM4669826 XP002283716  |                |
|                        | 8                     | DATABASE MEDLINE'ONLINE! US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; 1972 MURATOVA J ET AL: "EFFECT OF PYRAZOLIDINE DERIVATIVES ON EXPERIMENTAL VENOUS THROMBOSIS IN RABBITIS." DATABASE ACCESSION NO. NLM4273931 XP002283717.   |                |
|                        | 9                     | DATABASE CAPLUS 'ONLINE! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, OHIO, US; 1994 VAINIOTALO, P. ET AL: "N, N-COUPLED HETEROBICYCLES FROM CYCLIC HYDRAZINE DERIVATIVES. PART 6. ELECTRON IONIAZION MASS SPECTROMETRY OF SOME SUBSTITUTED 1-THIOCARBAMOYL AND 1-CARBAMOYLPYRAZLIDINES" RETRIEVED FROM STN DATABASE ACCESSION NO. 1994:190889 XP002283718 |                |
|                        | 10                    | DATABASE CAPLUS 'ONLINE! CHEMICAL ABSTRACTS SERVICE, COLUMBUS, HIO, US; 1973 ZINNER, G. ET AL: "CARBAMOYLATION OF HYDRAZINE DERIVATIVES" RETRIEVED FROM STN DATABASE ACCESSION NO. 1973:97543 XP002283719.  |                |
|                        | 11                    | DATABASE CAPLUS 'ONOINE! CHEMICAL ABSTRACTS SERVICE, COLUMBUS OHIO, US; 1972 BOLLBUCK, GUENTER ET AL: "REACTIONS OF 4-ARYL SEMICARBAZIDES" RETRIEVED FROM STN DATABASE ACCESSION NO. 1972:59168 XP002283720   |                |
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